K080529
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# 510(k) Summary

## Biospace med's sterEOS Workstation

AUG 29 2008

**Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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Contact Person: Karine Chevrie

Date Prepared: August 21, 2008

**Trade Name:**

sterEOS Workstation

**Common or Usual Name:**

sterEOS Workstation for the EOS

**Classification:**

21 CFR 892.2050; radiological image processing system

**Product Code:**

LLZ

**Predicate Devices:**

- Syngo Multimodality Workstation from Siemens Medical Systems, Inc. (K010938)
- Agfa Orthopedic Software for Impax Workstations (K071972)

**Device Description:**

The SterEOS Workstation is a general picture archiving and communications storage system for acceptance, transfer, display, storage, and digital processing of 2D x-ray images of the musculoskeletal system, including interactive 2D measurement tools.

When used with 2D X-ray images obtained with the Biospace EOS System (K071546), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of scoliosis and related disorders and deformities of the spine.

**Indications for Use:**

The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general PACS device for acceptance, transfer, display, storage, and digital processing of 2D x-ray images of the musculoskeletal system including interactive 2D measurement tools.

When using 2D X-ray images obtained with the Biospace EOS System (K071546), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients 16 years and older. The 3D measurement tools include interactive analysis based on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data. The model of bone structures is not intended for use in patients with a Cobb's angle > 50 degrees and is not intended for use to assess individual vertebral abnormalities

**Technological Characteristics:**

The sterEOS Workstation supports DICOM 3.0 formatted images. The Workstation is based on the Windows XP operating system and runs on off-the-shelf hardware. The sterEOS Workstation user interface follows typical clinical workflow patterns to process, review, and analyze digital images.

**Performance Data:**

A comparative study was conducted in a clinical setting to demonstrate accuracy of clinical parameters calculated in the 3D space. The results of this study validate the 3D reconstruction software and demonstrate the equivalent performance of the device.

**Substantial Equivalence:**

The sterEOS Workstation, when used as a general picture archiving and communications storage system, including the interactive 2D measurement tools, and when used with 2D X-ray images obtained with the Biospace EOS System (K071546), is as safe and effective as the Siemens Syngo Multimodality Workstation and the Agfa Orthopedic Software for Impax Workstation. The sterEOS Workstation, when used as a general PACS and with the 3D measurement tools available for use with the 2D X-ray images from the EOS System, has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the sterEOS Workstation and its predicate devices raise no new questions of safety or effectiveness. Thus, the sterEOS Workstation is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 29 2008

Biospace Med Incorporated
% John J. Smith, M.D., J.D., Partner
Hogan & Hartson, LLP
Columbia Square
555 Thirteenth Street, N.W.
WASHINGTON DC 20004

Re: K080529
Trade/Device Name: stereos Workstation
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: August 21, 2008
Received: August 21, 2008

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

**510(k) Number (if known)**: K080529

**Device Name:** sterEOS Workstation

The sterEOS Workstation is intended for use in the fields of musculoskeletal radiology and orthopedics in both pediatric and adult populations as a general PACS device for acceptance, transfer, display, storage, and digital processing of 2D x-ray images of the musculoskeletal system including interactive 2D measurement tools.

When using 2D X-ray images obtained with the Biospace EOS System (K071546), the sterEOS Workstation provides interactive 3D measurement tools to aid in the analysis of scoliosis and related disorders and deformities of the spine in adult patients as well as pediatric patients 16 years and older. The 3D measurement tools include interactive analysis based on a model of bone structures derived from an a priori image data set from 175 patients (91 normal patients, 47 patients with moderate idiopathic scoliosis and 37 patients with severe idiopathic scoliosis), and dry isolated vertebrae data. The model of bone structures is not intended for use in patients with a Cobb's angle > 50 degrees and is not intended for use to assess individual vertebral abnormalities

Prescription Use ___X__ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080529